

REMARKS

Claims 1, 5, 8, 9, 10 and 11 are amended, and claims 2-4, 6 and 12 are canceled; as a result, claims 1, 5, 7-11 are now pending in this application. The pending claims are fully supported by the specification as originally filed, and no new subject matter has been added.

Support for "*Salmonella*" in claim 1 is found in originally filed claim 5. Support for the term "*lsgG*" in claim 1 is found, for example, in the specification at page 5, lines 2-3.

Support for the term "*LsgG*" in claim 1 is found, for example, in the specification at page Example 6 and Figure 1.

Support for the phrase "*rfe* is regulated by *LsgG*" in claim 1 is found, for example, in the specification at page 5, lines 2-3 and page 7, lines 11-12.

Claim 9 has been amended to clarify that the LOS or LPS generated is a *Haemophilus influenzae*, *Neisseria spp.* or *Salmonella spp.*-specific LOS or LPS.

Claim 10 has been amended to have proper antecedent basis.

Claim 11 has been amended to correct a typographical error.

It is submitted that due to a typographical error, the term "glycotransferase" as opposed to the term "glycosyltransferase" appears in the specification

Information Disclosure Statement

A Corrected Information Disclosure Statement and Form 1449, showing the correct prior U.S. application serial number and filing date, which was relied upon for an earlier filing date under 35 U.S.C. § 120, is enclosed herewith.

Claim Objections

The examiner objected to the misspelling of "oligosaccharide" in claims 1, 11 and 12. Claims 1 and 11 have been amended to correct the misspelled term. Claim 12 has been cancelled. Therefore, this objection should be withdrawn.

§112 Rejection of the Claims

The Examiner rejected claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The cancellation of claim 12 renders this rejection moot.

Withdrawal of the 35 U.S.C. § 112, second paragraph, rejection is therefore respectfully requested.

§102 Rejection of the Claims

1. Rejection of claims 1-10 over Kwaik *et al.*

The Examiner rejected claims 1-10 under 35 U.S.C. § 102(b) as being anticipated by Kwaik *et al.* (Molecular Microbiology, 5, 2475-2480 (1991)). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q.2d 90 (Fed. Cir. 1986); In re Dillon, 16 U.S.P.Q.2d 1987 (Fed. Cir. 1990). Furthermore, there must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the art. Scripps Clinic & Res. Found. v. Genentech, Inc., 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Further, an anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. ATD Corp. v. Lydall Inc., 48 U.S.P.Q.2d 1321, 1328 (Fed. Cir. 1998) (*emphasis added*).

Kwaik *et al.* disclose the isolation of a recombinant phage containing a 14 kb insert from *Haemophilus influenzae* type B (Hib) that assembles an oligosaccharide on an *Escherichia coli* lipopolysaccharide (LPS) structure (abstract and page 2475, right column). Kwaik *et al.* further disclose that a 7.2 kb PstI-BamHI restriction fragment was sub-cloned from the 14 kb insert, and was found to contain a cluster of at least three genetic loci whose products act sequentially in LOS synthesis (page 2475). When the 7.2 kb PstI-BamHI restriction fragment was sub-cloned into an *E. coli*, Kwaik *et al.* disclose that the 4.1K *E. coli* LPS structure was modified, and the transformed *E. coli* generated either a 4.5K, 5.1K or 5.5K lipopolysaccharide species (abstract;

page 2475, right column). Kwaik *et al.* termed the three loci “*lsg-1*, -2 and -3” (page 2477, right column). Kwaik *et al.* disclose that the products of the *lsg-1* locus may recognize an *E. coli* LPS acceptor residue, and modification of *E. coli* LPS by *lsg-1* may be required for the functioning of other gene products encoded” by the cloned fragment (page 2477, right column). Alternatively, Kwaik *et al.* disclose that the fragment may be part of a complex operon that requires the presence of the *lsg-1* promoter for transcription, or *lsg-1* may encode a regulatory element (page 2477, right column; see also, the present specification at page 9, line 12).

Kwaik *et al.* do not disclose that a *Haemophilus influenzae*-specific LOS was formed on the host cell's LPS core structure, *i.e.*, that a chimeric carbohydrate had been produced in the transformed bacteria.

Further, there is nothing in Kwaik *et al.* that teaches or suggests *lsgG*, let alone that a glycotransferase could be used to regulate an enzyme such as is encoded by *rfe*. The present specification discloses that a chimeric carbohydrate could be produced by assembling a complex carbohydrate into a core LPS structure in a transformed bacterium, and such assemblage can be controlled by the unique interaction of *rfe* and *H. influenzae lsg*. For example, Applicants disclose that the *lsgG* gene product increases the expression of *rfe*. This results in the deposition of an N-acetylglucosamine on the terminal heptose in the core region. This is a novel activity for *rfe*, an enzyme previously shown to be involved in O-antigen biosynthesis. The N-acetylglucosamine can act as an acceptor for other glycotransferases to allow assembly of a variety of oligosaccharides on the core structure.

Moreover, the pending claims recite that the bacterium is a *Salmonella* bacterium. Kwaik *et al.* only disclose the use of *E. coli*. They do not teach that *Salmonella* could be effectively used in place of *E. coli*. Therefore Kwaik *et al.* does not anticipate the present claims.

Since all of the features of the present invention were not taught or suggested by Kwaik *et al.*, the pending claims are not anticipated by this article. Withdrawal of this 35 U.S.C. § 102(b) rejection is therefore respectfully requested.

2. Rejection of claim 12 over Kwaik *et al.* in light of Westphal *et al.*

The Examiner rejected claim 12 under 35 U.S.C. § 102(b) as being anticipated by Kwaik *et al.* in light of Westphal *et al.* ("Methods in Carbohydrate Chemistry," Whistler *et al.*, eds., vol. 5, pp. 83-91, Academic Press, New York, (1964)). Claim 12 has been cancelled, thereby rendering this rejection moot.

3. Rejection of Claims 1-3, 5 and 10-12 over Brade *et al.*

Claims 1-3, 5 and 10-12 were rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Brade *et al.* (Infection and Immunity, 55 482-486 (1987)). As these rejections may be maintained with respect to the pending claims, they are respectfully traversed.

The Examiner has indicated that Brade *et al.* does not read on claim 4. The pending claims have been amended to recite that the bacterium contains an *lsgG* regulatory gene, as recited by claim 4. Therefore, withdrawal of this 35 U.S.C. § 102(b) rejection is therefore respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) ~~373-6961~~³⁷¹⁻²¹⁰⁶) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

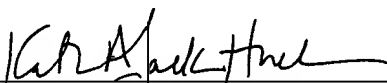
Respectfully submitted,

MICHAEL A. APICELLA ET AL.

By their Representatives,

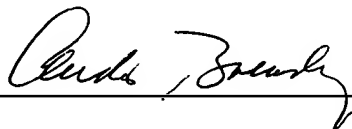
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) ~~373-6961~~ 371-2106

Date 29 October 2003

By 
Katherine A. Jackson Huebsch
Reg. No. 47,670

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of October, 2003.

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